MAR 11 2008

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Special 510(k)

K080423

Attachment 5: 510(k) Summary

*Submitter's Name:	Ellex Medical Pty. Ltd. *Manufacturing and packaging.*
Submitter's Address:	82 Gilbert Street Adelaide, South Australia, 5000 AUSTRALIA
Contact Person:	Kevin Howard, Senior Regulatory Officer
Contact Details:	Tel +61 8 8104 5200 Fax +61 8 8221 5645 Email: khoward@ellex.com
Date Summary Prepared:	December 13, 2007
Trade Name of Modified Device: (For which this Special 510(k) is being submitted)	Integre LP561
Common Name of Modified Device: (For which this Special 510(k) is being submitted)	Photocoagulator Ophthalmic Laser
Classification of Device:	Class II, HQF; GEX, Ophthalmic Laser
Trade Name of Predicate Device:	Ellex Integre Duo LP1RG
Common of Predicate Device:	Photocoagulator Ophthalmic Laser
Classification of Device:	Class II, Ophthalmic Laser
Description of the Device:	The Integre LP561 is an addition to the Ellex range of ophthalmic photocoagulators. The Integre family are designed for use by ophthalmologists in a clinic or outpatient facility, or in the Retinal Specialist's office. The Integre Duo LP1RG device is capable of producing focused pulses of red or green light with wavelengths of 670 nanometres (nm) and 532 nm respectively. The red and green beams may be used for the same treatments, but the red gives increased penetration of haemorrhaging tissue and fluids, and may also be used to treat ocular melanomas. The Integre LP561 is essentially the same device with a modification to the laser cavity optical components which results in a yellow (561 nm) treatment laser output. The reason for developing the new device is because the yellow wavelength is characterised by high absorption by melanin in the retinal pigment epithelium and choroids that reduces the

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penetration depth of the beam in the choroids, high absorption by haemoglobin that facilitates direct treatment for retinal/choroidal neovascularisation and no absorption in macular xanthophylls and higher transmission through cloudy media such as cataract or haze on the cornea.

As with the Integre LP1RG, the laser pulses are accurately positioned on a structure within the patient's eye with the aid of a delivery device. The delivery device is an integrated slit-lamp microscope. An optional Laser Indirect Ophthalmoscope (LIO) can also be used.

Intended Use:

The Integre Duo is a ophthalmic photocoagulator laser designed to be used by ophthalmologists for treatment of ocular pathology of the eye. It is expected that the user is trained in operation of the instrument. This is the same intended use as previously cleared for Integre Duo laser 510(k) K052777
The Indications for Use statement can be found in Attachment 2

Comparison of Technological Characteristics:

Refer to the following tables for a comparison of the Integre LP561 with the Integre Duo LP1RG and other commercially available predicate devices

Comparison Table – Treatment lasers of devices

Characteristic compared	Integre LP561	Integre Duo LP1RG; 510(k) K052777	Lumenis Novus Varia; 510(k) K022181	Nidek MC-7000; 510(k) K974732	Nidek MC-300; 510(k) K042785
Laser Type	True CW Diode-Pumped Solid-State (DPSS)	True CW Diode-Pumped Solid-State (DPSS)	Diode-Pumped Solid-State (DPSS)	Diode-Pumped Solid-State (DPSS) frequency-doubled YAG	Diode-Pumped Solid-State (DPSS) frequency-doubled YAG
Laser Wavelength	561 nm (yellow)	532 nm (green) 670 nm (red)	532 nm (green) 561 nm (yellow) 659 nm (red)	520.8-530.9 nm (green) 568.2 nm (yellow) 647.1 nm (red)	532 nm (green) 561 nm (yellow) 659 nm (red)
Laser Power	50-1500 mW (yellow)	50-2000 mW (green) 50-1500 mW (red)	50-1500 mW (green) 50-600 mW (yellow) 50-600 mW (red)	50-900 mW (green) 50-1500 mW (yellow/green) 50-1000 mW (red)	50-2000 mW (green) 50-700 mW (yellow) 50-700 mW (red)
Exposure time settings (pulse duration)	0.01 to 4.0 seconds adjustable in variable increments	0.01 to 4.0 seconds adjustable in variable increments	0.01 to 3.0 seconds adjustable in variable increments	0.02 seconds to continuous adjustable in 21 increments	0.01 to 3.0 seconds adjustable in variable increments
Repeat mode intervals	0.1 to 1.0 seconds	0.1 to 1.0 seconds	0.05 to 3.0	0.2 to 1.0 seconds	0.2 to 1.0 seconds
Laser Safety Class	4/IV	4/IV	4/IV	4/IV	4/IV
Spot Size	50 to 1000 µm	50 to 1000 µm	50 to 1000 µm	50 to 1000 µm parfocal, 1000 to 2000 µm defocused	50 to 900 µm

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Comparison Table – Aiming lasers of devices

Characteristic compared	Integre LP561	Integre Duo LP1RG	Lumenis Novus Varia	Nidek MC-7000	Nidek MC-300
Aiming Laser Type	Semi conductor laser diode	Semi conductor laser diode	Semi conductor laser diode	Semi conductor laser diode	Diode pumped solid-state
Aiming Laser Power	<1 mW	<1 mW	<1 mW	<1 mW	0.3-0.7 mW Red 0.05-0.15 mW Yellow/Green
Aiming Wavelength	635 -5/+10 nm	635 -5/+10 nm	635 nm	670 nm	532/561/659 nm
Laser Safety Class	2/II	2/II	2/II	2/II	2/II

Comparison Table – Electrical and Mechanical Characteristics of Devices

Characteristic compared	Integre LP561	Integre Duo LP1RG	Lumenis Novus Varia	Nidek MC-7000	Nidek MC-300
Mains Electrical Supply Voltage	90-240VAC; 250VA	90-240VAC; 250VA	100VAC, 120VAC or 230VAC; 880VA	90-245 VAC, 3 phase	100/115/230 VAC
Supply Frequency	50/60Hz	50/60Hz	50/60Hz	50/60Hz	50/60Hz
Weight	console 14.5 kg slit lamp 10.5 kg	console 14.5 kg slit lamp 10.5 kg	52.2 kg	176 kg	75 kg
Size	Console H140 x W280 x D350 mm	Console H140 x W280 x D350 mm	H1020 x W460 x D640mm	Console 406 x 990 x 1219 mm	Console H780 x W350 x D725 mm
Operating Temperature Range	+10 C to +40 C; RH 10 to 85%	+10 C to +40 C; RH 10 to 85%	10 C to 37°C; RH 90% @ 37 C non-condensing		15-30°C, RH 30-75% non-condensing
Transport & Storage Temperature Range	-20 C to +60 C; RH 10% to 85%	-20 C to +60 C; RH 10% to 85%	-10 C to 55°C; RH 90% @ 55°C non-condensing		0-50°C, RH 5-95% non-condensing
Cooling (console)	Air cooled with integrated active thermo-electric cooler	Air cooled with integrated active thermo-electric cooler	Forced air with integrated Thermo Electric Cooler	Internal Water Cooling	Digital control cooling device (internal water cooling)

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Comparison Table –Delivery Devices & Accessories

Delivery Device	Integre LP561	Integre Duo LP1RG	Lumenis Novus Varia	Nidek MC-7000	Nidek MC-300
Slit Lamp Delivery System (SDS)	Treatment & aiming lasers integrated into slit lamp microscope.	Treatment & aiming lasers integrated into slit lamp microscope.	LaserLink Z and LaserLink Z-1000- slit-lamp delivery adaptors	May be used with; Nidek SL1600, Zeiss SL130, Haag Striet 900BQ	May be used with; - Nidek slit lamp delivery unit (SL-1800 type) - Nidek attachable slit lamp delivery unit (attachable to SL-1600) - Zeiss slit lamp delivery unit (attachable to 30SL/M type)
Laser Indirect Ophthalmoscope (LIO)	Ellex LIO.	Ellex LIO.	Keeler, Heine	BIO (Heine or Keeler), MIO (Neitz)	BIO (Keeler)
Endo Ocular Laser Probe	Not available	Not available	Acculite angled, straight, illuminating and aspirating probes	Endophotocoagulation probe, straight, angled, illuminated & combined	Endophotocoagulation probe, straight, angled, illuminated & combined
Accessory	**Integre LP561**	**Integre Duo LP1RG**	**Lumenis Novus Varia**	**Nidek MC-7000**	**Nidek MC-300**
Footswitch	Standard footswitch provided as a standard system component. Power control footswitch accessory available.	Standard footswitch provided as a standard system component. Power control footswitch accessory available.	Provided as a standard system component Smart & Powerease footswitch accessory available	Provided as a standard system component	Provided as a standard system component Power Control footswitch accessory available
Remote Control	Provided as a standard system component.	Provided as a standard system component.	Remote control	Provided as a standard system component	Provided as a standard system component
Safety Filter	Moveable eye safety filter.	Moveable eye safety filter.	Dual physician filters	Fixed colour balanced safety filter provided as standard system component	

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Comparison - Indications for Use of Devices

New Device

Integre LP561

The Ellex Integre is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation and pan retinal photocoagulation of vascular and structural abnormalities of the retina and choroid including:
  - proliferative and nonproliferative diabetic retinopathy;
  - choroidal neovascularization;
  - branch retinal vein occlusion;
  - age-related macular degeneration
  - retinal tears and detachments
  - retinopathy of prematurity
- Iridotomy, iridectomy, suturelysis and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Integre Duo LP1RG 510(k) K052777

The Ellex Duo is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation and pan retinal photocoagulation of vascular and structural abnormalities of the retina and choroid including:
  - proliferative and nonproliferative diabetic retinopathy;
  - choroidal neovascularization;
  - branch retinal vein occlusion;
  - age-related macular degeneration
  - retinal tears and detachments
  - retinopathy of prematurity
- Iridotomy, iridectomy, suturelysis and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Lumenis Novus Varia 510(k) K022181

Photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation, pan retinal photocoagulation and intravitreal

Endo-photocoagulation of vascular and structural abnormalities of the retina and choroid including:

- proliferative and nonproliferative diabetic retinopathy;
- choroidal neovascularization;
- branch retinal vein occlusion;
- age-related macular degeneration
- retinal tears and detachments
- retinopathy of prematurity

- Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Nidek MC-7000 510(k) K974732

Transpupillary:

- Retinal Photocoagulation, either limited or Pan-Retinal Photocoagulation
- Macular Photocoagulation
- Trabeculoplasty for open angle glaucoma
- Iridotomy for acute angle closure

Inter-operative

- Retinal photocoagulation, either limited or Pan-retinal
- Macular Photocoagulation

Nidek MC-300 510(k) K042785

Used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ellex Medical Pty. Ltd.
c/o Kevin Howard
Senior Regulatory Officer
82 Gilbert Street
Adelaide, SA 5000
Australia

MAR 11 2008

Re: K080423
Trade/Device Name: Integre LP561
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: February 13, 2008
Received: February 15, 2008

Dear Mr. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K080423

Device Name: Ellex Integre LP561 ophthalmic laser.

Indications for Use:

The Ellex Integre is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation and pan retinal photocoagulation of vascular and structural abnormalities of the retina and choroid including:
  - proliferative and nonproliferative diabetic retinopathy;
  - choroidal neovascularization;
  - branch retinal vein occlusion;
  - age-related macular degeneration;
  - retinal tears and detachments;
  - retinopathy of prematurity;
- Iridotomy, iridectomy, suturelysis and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/10/2008

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K080423